

Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 20 and 54 have been amended to clarify the position where the third and fourth oligonucleotide primers anneal to the sample single-stranded nucleic acid molecule and the first single-stranded nucleic acid molecule, respectively. Descriptive support for this limitation is noted below. Claims 20, 22, and 54-59 remain pending, with claims 20 and 22 standing withdrawn.

Initially, applicants request withdrawal of the restriction and rejoinder of claims 20 and 22 with claims 54-59. The three components of the claimed kit (of claim 20) are recited for use in the claimed method of claims 54-59. Therefore, as previously noted, any search for the subject matter of claims 20 and 22 will be coextensive with the search for the subject matter of claims 54-59. In other words, there is no additional search burden to consider the subject matter of claims 20 and 22.

Concerning the U.S. Patent and Trademark Office (“PTO”) interpretation of the term “sequence” as it is used in the claim limitations “3’ terminal nucleotide sequence” and “5’ terminal nucleotide sequence,” applicants respectfully submit that it is improper. The term “sequence” connotes an arrangement of two or more nucleotides in succession (i.e., from 5’ to 3’ direction). A single nucleotide does not possess a sequence. As stated in the specification at page 27, lines 15-20, the primers preferably possess an annealing part that is longer than 5 bases, more preferably 10 bases or more. These preferred lengths are consistent with a definition of sequence being two or more nucleotides in succession.

The rejection of claims 54-59 under 35 U.S.C. § 112 (second para.) for indefiniteness is respectfully traversed in view of the above amendments and the following remarks. The third and fourth primers are defined by the regions where they anneal to the sample single-stranded nucleic acid molecule and the first single-stranded nucleic acid molecule, respectively. This annealing region is defined by two criteria. The first criterion is that the annealing region is located 3’ to region where the first or second primers anneal to the sample single-stranded nucleic acid molecule or first single-stranded nucleic acid molecule, respectively. The second criterion is that the annealing region is outside of a region defined by the outer nucleotides of the first or second oligonucleotide primers. As shown in Figure 1 at step (2), the third primer bearing sequence “F3” anneals to region “F3c”, which is located

3' to the region "F2c," where the first primer "FA" anneals, and outside of a region defined by the outer nucleotides of the first primer. Likewise, as shown in Figure 2 at step (5), the fourth primer bearing sequence "R3" anneals to region "R3c", which is located 3' to the region "R2c" where the second primer "RA" anneals, and outside of a region defined by the outer nucleotides of the second primer. Because the recited language is not unclear, the rejection should be withdrawn.

The rejection of claims 54, 58, and 59 under 35 U.S.C. § 102(b) as anticipated by PCT Application Publ. No. WO 95/03426 to Cleuziat et al. ("Cleuziat"), as evidenced by U.S. Patent No. 5,849,547 to Cleuziat et al., is respectfully traversed.

Fig. 3 of Cleuziat only shows introduction of an RNA polymerase promoter sequence into a template. The inner primers (A, B) used in Cleuziat have two segments capable of hybridizing with the RNA polymerase promoter sequence and the template, respectively. These primers do not contain a 5' terminal nucleotide sequence that is complementary to an arbitrary region of the extension product (and contributes to loop formation at the 3' end). (As noted above, the term "sequence" connotes two or more nucleotides, not just a single nucleotide as suggested by the PTO.) That Cleuziat's inner primers lack this feature is evident in the displaced extension products IV and IV', which are shown not to possess a 3' loop formation. Nowhere does Cleuziat suggest that the extension products IV and IV' are capable of self-extension from their 3' end, which would be possible if a 3' loop formed. Therefore, the primers (A,B) used in Cleuziat are both structurally and functionally different from the inner primers of the present invention (i.e., the first primer and second primer according to claim 54).

Because Cleuziat fails to teach or suggest each and every limitation of the claimed invention, claims 54, 58, and 59 are not anticipated by Cleuziat. This rejection is improper and should therefore be withdrawn.

The rejection of claims 55-57 under 35 U.S.C. § 103(c) for obviousness over Cleuziat in view of U.S. Patent No. 5,972,618 to Bloch et al. ("Bloch") is respectfully traversed.

The teaching and deficiencies of Cleuziat are noted above. Bloch is cited solely for the use of melting temperature regulators. The PTO has failed to demonstrate how Bloch overcomes the above-noted deficiencies of Cleuziat with respect to independent claim 54. Because claim 54 is patentable for the reasons noted above, and claims 55-57 depend

from claim 54, the obviousness rejection over Cleuziat in view of Bloch is improper and should be withdrawn.

The rejection of claim 54 for obviousness type double-patenting over claims 5, 12, and 13 of U.S. Patent No. 6,410,278 to Notomi et al. is respectfully traversed in view of the accompanying Terminal Disclaimer.

The rejection of claim 54 for obviousness type double-patenting over claims 3, 4, 27, and 28 of U.S. Patent No. 6,974,670 to Notomi et al. is respectfully traversed in view of the accompanying Terminal Disclaimer.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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